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THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

WYETH,
a Delaware Corporation,

and

GENETICS INSTITUTE LLC
a Delaware Limited Liability Company,

Plaintiffs,

vs.

THE TRUSTEES OF COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK,
a New York Corporation,

Defendant.

COMPLAINT FOR DECLARATORY
JUDGMENT AND INJUNCTIVE
RELIEF

03cv11570 MLW

COMPLAINT

Introduction

1. In 1983, The Trustees of Columbia University in the City of New York (“Columbia”) obtained a patent relating to recombinant DNA and a process called “cotransformation.” The National Institute of Health, Department of Health and Human Services (“HHS”) funded the research that led to this invention, and granted Columbia “title” to the invention, with conditions. Among these was the condition that “any license granted by [Columbia] shall include adequate safeguards against unreasonable royalties and repressive practices.” In 1987 and 1993, Columbia obtained two additional related patents concerning cotransformation. These three patents (the “Axel patents”) all expired on August 16, 2000.

2. Upon information and belief, in the past two decades, Columbia licensed the Axel patents to more than two-dozen companies, including a license dated July 31, 1990 with Genetics Institute, Inc., which was subsequently acquired by Wyeth (the “License Agreement”) (Plaintiffs Wyeth and Genetics Institute LLC (the successor of Genetics Institute, Inc.) are collectively referred to herein as “Wyeth” unless specifically stated otherwise). Upon information and belief, Columbia has received nearly 400 million dollars in royalties from those companies – over 27 million dollars from Wyeth alone. Columbia has thus obtained the full benefits of the patent coverage on its government-funded invention.

3. When the Axel patents expired on August 16, 2000, the invention passed into the public domain and, therefore, the public, including Wyeth, became entitled to manufacture products covered by the invention in the United States free from any royalty obligations. Nonetheless, more than two years after those patents expired, Columbia obtained a new U.S. patent on the invention – U.S. Patent No. 6,455,275 (“‘275 patent”) – a child of Columbia’s previously expired Axel patents. The ‘275 patent has the same specification as, and improperly claims the same subject matter as claimed in the original, expired Axel patents. On the basis of this new patent, Columbia seeks to extract from Wyeth (and, upon information and belief, nearly the entire biopharmaceutical industry) continued royalties under the License Agreement potentially until this patent expires in 2019. This potential nineteen year extension on its patent monopoly (which includes two years during which there was not even a patent in force) is not only grossly improper, but is wholly unfair to the public, who initially paid for the research that led to the invention, and to its licensees, including Wyeth, which have already paid hundreds of millions of dollars in royalties to Columbia on patents that are now expired.

4. Wyeth brings this action for a declaration that the ‘275 patent is invalid and unenforceable because of, *inter alia*, the prohibition against “double-patenting” and Columbia’s

laches and inequitable conduct in the prosecution of the patent application. Wyeth further requests, *inter alia*, a declaratory judgment that, contrary to the contentions of Columbia, Wyeth is under no obligation to pay Columbia royalties and fees under the '275 patent, the patent applications pending prior to issuance of the '275 patent, or any additional pending patent applications claiming priority to the original Axel patent application, and that Wyeth is entitled to repayment of any royalties and fees paid to Columbia based on the '275 patent or pending patent applications.

THE PARTIES

5. Genetics Institute LLC is a Delaware limited liability company with a principal place of business at 35 CambridgePark Drive, Cambridge, Massachusetts 02140, and is qualified to do business in the State of Massachusetts. Genetics Institute LLC also is the owner of two facilities in Massachusetts – one in Cambridge and a second in Andover. Genetics Institute LLC came into existence as of January 1, 2002, when Genetics Institute, Inc. was converted into Genetics Institute LLC. Genetics Institute, Inc. is no longer in existence. Genetics Institute, Inc. was the original party to the License Agreement (“Licensing Agreement relating to U.S. Patent No. 4,399,216 et al.”). By operation of the conversion, Genetics Institute LLC is the current party to the License Agreement. Through a series of transactions, Genetics Institute LLC became and currently is a wholly-owned subsidiary of Wyeth.

6. Wyeth is a Delaware corporation with a principal place of business at Five Giralda Farms, Madison, New Jersey 07940. Wyeth was formerly known as American Home Products Corporation. By its terms, the License Agreement extends to Wyeth, as an affiliate of Genetics Institute LLC, and Wyeth operates under the License Agreement. Wyeth expends considerable resources in research and development of pharmaceuticals and biopharmaceuticals, resulting in the development of a variety of products, including neuroscience therapies, cardiovascular

products, nutritionals, gastroenterology drugs, anti-infectives, vaccines, oncology therapies, musculoskeletal therapies, hemophilia treatments and immunological products. Wyeth, through its various divisions, employs nearly 3,000 people in this judicial district. Wyeth does business globally, including in this judicial district.

7. Upon information and belief, Columbia is a New York corporation, with a principal place of business in New York, New York.

JURISDICTION

8. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), 2202, and the Court's supplemental jurisdiction under 28 U.S.C. § 1367(a). Also, because the amount in controversy exceeds \$75,000, and the action is between citizens of different states, the Court has jurisdiction under 28 U.S.C. § 1332(a)(1).

VENUE

9. Venue is proper in this district under 28 U.S.C. § 1391(b). Columbia negotiated and entered into the License Agreement with Genetics Institute, Inc., located in this judicial district, and Wyeth and several of its divisions are residents of this judicial district; Genetics Institute, Inc. signed the License Agreement in this judicial district; Columbia has directed substantial communications regarding the License Agreement and the '275 patent to Wyeth in this judicial district; Columbia has accepted from Wyeth substantial sums of money originating from this district pursuant to the License Agreement; and Wyeth, through its divisions, manufactures several of its biotechnology products in this judicial district.

FACTS COMMON TO ALL CLAIMS FOR RELIEF

Columbia Obtained U.S. Patents that Expired on August 16, 2000

10. On February 25, 1980, Columbia filed U.S. Patent Application No. 06/124,513 ("513 application"), the original cotransformation patent application. The invention described

in the '513 application was based upon research performed under grants from HHS. The '513 application has resulted in the issuance of several U.S. patents that were assigned to Columbia.

11. The first such patent, U.S. Patent No. 4,399,216 ("216 patent"), was issued August 16, 1983, and was entitled "Processes for Inserting DNA into Eucaryotic Cells and for Producing Proteinaceous Materials." The '216 patent identifies Richard Axel, Michael H. Wigler and Saul J. Silverstein as inventors. A true copy of the '216 patent is attached hereto as Exhibit 1. The '216 patent expired on August 16, 2000.

12. The second such patent, U.S. Patent No. 4,634,665 ("665 patent"), was issued January 6, 1987 to Columbia based on an identical disclosure. It was entitled "Processes for Inserting DNA into Eucaryotic Cells and for Producing Proteinaceous Materials," and resulted from a continuation application from the application that matured into the '216 patent. A true copy of the '665 patent is attached hereto as Exhibit 2. In order to secure allowance of the '665 patent in the face of double-patenting rejections, Columbia was required to file a terminal disclaimer by which Columbia agreed that the term of the '665 patent would not extend beyond the August 16, 2000 expiration date of the '216 patent. Pursuant to the terminal disclaimer, the '665 patent expired on August 16, 2000.

13. The third such patent, U.S. Patent No. 5,179,017 ("017 patent"), was issued January 12, 1993, to Columbia based on an identical disclosure. It was entitled "Processes for Inserting DNA into Eucaryotic Cells and for Producing Proteinaceous Materials," and resulted from a continuation of the application that had led to the '665 patent. A true copy of the '017 patent is attached hereto as Exhibit 3. In order to secure allowance of the '017 patent in the face of double-patenting rejections, Columbia again was required to file a terminal disclaimer by which Columbia agreed that the term of the '017 patent would not extend beyond the August 16,

2000 expiration date of the '216 patent. Pursuant to the terminal disclaimer, the '017 patent expired on August 16, 2000.

14. From August 16, 1983, when the '216 patent issued, through the expiration of the '216, '665 and '017 patents on August 16, 2000, Columbia profited greatly from these patents. Plaintiffs are informed and believe that Columbia has licensed these patents to more than two dozen companies and has received nearly 400 million dollars by reason of these three patents. Since 1990, Wyeth alone has paid Columbia over 27 million dollars in royalties and fees.

After Expiration of the Three U.S. Patents, Columbia Obtained the '275 Patent

15. Columbia has pursued a two-pronged approach to extend its exclusive rights. First, Columbia engaged in an extensive, but ultimately unsuccessful attempt to lobby Congress to extend the life of the '216 patent. Second, Columbia pursued a strategy of delay at the U.S. Patent and Trademark Office ("PTO") that included the repeated practice of abandonment coupled with filing continuation applications in an effort to obtain another patent with claims directed to the same subject matter and with an additional seventeen-year term.

16. In particular, just before issuance of the '017 patent on January 12, 1993, Columbia submitted the first of a chain of four consecutive patent applications that eventually led to the issuance of Columbia's fourth patent relevant to this action, the '275 patent. The first patent application in the chain was filed in 1992 and claimed priority to the original Axel patent application filed in 1980, more than twelve years earlier. This 1992 applications was later abandoned in 1994 in favor of the second patent application in the chain. This second patent application was abandoned in February 1995 in favor of the third patent application in the chain. This third application was abandoned on June 7, 1995 in favor of the fourth patent application in the chain, which ultimately issued in 2002 as the '275 patent.

17. Of interest, this fourth patent application was filed on the day before the GATT amendments, a significant change in the patent laws, took effect. Pursuant to the GATT provisions, patents granted or pending prior to June 8, 1995 would have a term of the longer of seventeen years from issuance or twenty years from filing of the first priority application. In contrast, patent applications filed from June 8, 1995 forward would have a term of twenty years from filing of the first priority application. Thus, under the new rules, the '275 patent, with a priority date of February 25, 1980, would have expired before it even issued. By filing on June 7, 1995, Columbia removed any incentive to diligently prosecute the patent application to issuance. In fact, this fourth application was pending before the PTO for over seven years, during which time Columbia engaged in a series of delay tactics, including seeking numerous extensions of time and filing two notices of appeal which it did not pursue. Columbia's dilatory prosecution tactics, resulted in an unreasonable delay in prosecuting the '275 patent claims. Accordingly, the '275 patent is invalid and unenforceable under the doctrine of prosecution laches.

18. Further, prior to the issuance of the '275 patent, Wyeth developed rights to the claimed technology, including the legal and equitable right to practice the invention(s) disclosed in the '513 application and/or claimed in the '216, '665 and '017 patents after August 16, 2000 free from any royalty obligations.

19. The '275 patent was issued to Columbia on September 24, 2002, and was based on a disclosure identical to the '216 patent (and the '665 and '017 patents). The '275 patent is entitled "DNA Construct for Producing Proteinaceous Materials in Eucaryotic Cells," and claims the same priority date as the prior three patents. However, unlike the '665 and '017 patents, in securing the '275 patent Columbia did not enter a terminal disclaimer. Thus, the '275 patent does not expire until 2019. A true copy of the '275 patent is attached hereto as Exhibit 4.

20. The research that led to the original patent application was funded under grants from HHS. In response to a petition from Columbia, in a letter agreement dated February 24, 1981 and executed by Columbia on October 5, 1983 (“the Columbia/HHS letter agreement”), HHS granted title to the invention to Columbia, but only upon certain conditions. Among these was the condition that any license “shall include adequate safeguards against unreasonable royalties and repressive practices.” Despite this condition, Columbia would have Wyeth – and the majority of the biopharmaceutical industry – paying royalties under the License Agreement until the ‘275 patent expires in 2019, and therefore Wyeth potentially would be paying royalties for a total of twenty-nine years. Such a position violates the conditions for granting title of the invention to Columbia.

21. The Columbia/HHS letter agreement also provided for circumstances wherein the rights to the U.S. patent applications or patents could revert back to the government. HHS also reserved the right to license or require the granting of a non-exclusive or exclusive license on a royalty-free basis or on terms that are reasonable in the circumstances.

22. The License Agreement further provides that “[a]ll rights granted by Columbia under this agreement are subject to any rights required to be granted to the Government of the United States of America, including without limitation any rights reserved or obligations imposed by the Government pursuant to 35 U.S.C. § 200-211, regulations thereunder and the determination letter to Columbia from the Department of Health and Human Services dated February 24, 1981, a copy of which is attached hereto...” and the 1981 letter agreement was attached as an exhibit to the License Agreement. The License Agreement thereby incorporates by reference the letter agreement, including all of Columbia’s obligations to HHS and the conditional nature of the patent title grant. A true copy of the Columbia/HHS letter agreement is attached hereto as Exhibit 5.

Columbia's Demand for Continued Royalties and Fees

23. By letters of January 29, 2001, August 8, 2001, November 5, 2001, and August 6, 2002, Columbia has demanded continued royalties and fees based on activities after August 16, 2000. Wyeth disagrees that any such royalties and fees are due.

FIRST CLAIM FOR RELIEF

Declaratory Judgment that the '275 Patent is Invalid

24. Wyeth incorporates and realleges all prior paragraphs of this complaint.

25. The claims of the '275 patent are invalid because each of the inventions claimed in it is identical to, or is merely an obvious variation of, the inventions claimed in the '216, '665 and/or '017 patents.

26. Accordingly, Wyeth desires a declaratory judgment that the '275 patent is invalid because each of the inventions claimed in it is identical to, or is merely an obvious variation of, the inventions claimed in the '216, '665 and/or '017 patents.

27. Wyeth also desires a declaratory judgment that the '275 patent is invalid for failing to satisfy the one or more of the statutory conditions of patentability set forth in 35 U.S.C. § 102, § 103 and § 112.

28. There is a case or controversy between the parties concerning the validity of the '275 patent.

29. Wyeth, therefore, respectfully seeks judgment as hereinafter set forth.

SECOND CLAIM FOR RELIEF

Declaratory Judgment that the '275 Patent Is Invalid and Unenforceable By Reason of Prosecution Laches

30. Wyeth incorporates and realleges all prior paragraphs of this complaint.

31. The patent claims of the '275 patent issued after unreasonable and unexplained delays in the prosecution of those claims. Columbia took twenty-two years from the filing of the priority document to obtain the '275 patent. Prosecution of the application from which the '275 patent directly issued alone took over seven years. Columbia consciously delayed the prosecution of the '275 patent, potentially resulting in a nineteen-year extension on its patent monopoly. As a result of this delay, enforcement of the '275 patent has caused and will cause Wyeth to suffer material prejudice.

32. During the period of this delay Wyeth developed rights in the claimed technology, including, the legal and equitable right to practice the invention disclosed in the '513 application and/or claimed in the '216, '665 and '017 patents after August 16, 2000 free from any royalty obligations. As a result of this delay, enforcement of the '275 patent has caused and will cause Wyeth to suffer material prejudice.

33. Despite the unreasonable and unexplained delays in prosecution, Columbia maintains that the '275 patent is valid and enforceable. There is a case or controversy between the parties about whether the '275 patent is invalid and unenforceable due to prosecution laches.

34. Accordingly, Wyeth desires a declaratory judgment that the '275 patent is invalid and unenforceable because of prosecution laches.

35. Wyeth, therefore, respectfully seeks judgment as hereinafter set forth.

THIRD CLAIM FOR RELIEF

Declaratory Judgment that the '275 Patent is Unenforceable due to Inequitable Conduct

36. Wyeth incorporates and realleges all prior paragraphs of this complaint.

37. Plaintiffs are entitled to and seek a declaratory judgement that the '275 patent is unenforceable by reason of inequitable conduct. More particularly, Columbia (a) advanced

misleading statements to the examiner about whether its claims were patentable, (b) failed to make timely disclosure of a related application and its prosecution history, (c) failed to disclose another of Dr. Axel's patents—U.S. Patent No. 5,149,636 (“‘636 patent”)—and its prosecution history despite the fact that some of its claims were rejected as being anticipated or obvious in view of the ‘216 patent, and (d) failed to disclose statements it had made to Congress that were inconsistent with positions it took during prosecution of the ‘275 patent.

38. There is an actual controversy between plaintiffs and Columbia concerning the unenforceability of the ‘275 patent for inequitable conduct.

A. Misleading Statements Regarding the Patentability of Claims of the ‘275 Patent

39. The ‘216, ‘665 and ‘017 patents all relied upon the same original disclosure and all expired in August 2000. To overcome double-patenting rejections, Columbia filed terminal disclaimers that ended the term of the ‘665 patent and the ‘017 patent on the expiration date of the ‘216 patent.

40. During prosecution of the ‘275 patent, in an Office Action dated February 3, 1998, the examiner rejected all pending claims for double patenting over the issued claims of the ‘017 patent. These rejected claims, then numbered 126-132, were drawn to DNA constructs for transforming cells and, in the case of claim 132, eukaryotic cells transformed using such constructs.

41. In response to the February 3, 1998 Office Action, on July 24, 1998, Columbia canceled claim 132, the only claim to transformed eukaryotic cells then pending. Columbia also argued that the remaining DNA construct claims were not subject to a double-patenting rejection over the ‘017 patent. Columbia stated: “The ‘right to exclude’ provided by claims 1-4 of U.S. 5,179,017 relates to transformed Chinese Hamster Ovary (CHO) cells. Thus, the ‘right to exclude’ provided by U.S. 5,179,017 relates only to the manufacture, use and sale of CHO cells.

In contrast, the ‘right to exclude’ which would be provided by claims 126-131 of the subject application would, if allowed, relate to the manufacture, use and sale of DNA constructs.” July 24, 1998 Response, pp. 2-3 (emphasis in original). Thus, Columbia acknowledged that the claims that issued in the ‘017 patent relate to transformed CHO cells.

42. During prosecution of the ‘275 patent, in an Amendment filed June 14, 2001, Columbia added numerous new claims, some of which ultimately issued in the ‘275 patent. The Remarks accompanying this amendment stated that the new claims were “not subject to the obviousness-type double-patenting rejection.” It then listed the claims in groups and explained why each group allegedly was not subject to rejection on double-patenting grounds. In each case, however, Columbia presented argument only about why the claims were not subject to double patenting in view of the ‘216 patent, not the ‘017 patent. Upon information and belief, Columbia made these statements preemptively, to deter the newly assigned examiner from issuing double-patenting rejections.

43. In asserting that the new claims in application serial No. 08/484,136 (“‘136 application”) (which led to the ‘275 patent) were not subject to double-patenting rejections over the ‘216 patent, Columbia misled the PTO by failing to draw the new examiner’s attention to the claims of Columbia’s other patents, and most significantly the ‘017 patent. The claims of the ‘017 patent, which provided the basis for double-patenting rejections in 1998 by the examiner at that time, are substantially similar to the new claims Columbia added to the ‘136 application in June 2001 and would have provided a basis for a double-patenting rejection of the new claims.

44. Columbia’s statement that the new claims should not be rejected over the ‘216 patent, while failing to draw the examiner’s attention to grounds for rejection over the ‘017 patent, was misleading because it implied that the ‘216 patent was the only basis upon which a double-patenting rejection could be made. Upon information and belief, in view of its statements

conceding that the '017 patent relates to transformed CHO cells, Columbia was aware that the newly asserted claims, many of which were directed to transformed CHO cells, were vulnerable to double-patenting rejections over the '017 patent claims. Upon information and belief, Columbia's misleading omission of its other issued patents, particularly the '017 patent, was a deliberate and intentional effort to draw attention away from the other grounds on which the claims could be rejected for double patenting and thus to mislead the examiner.

45. Moreover, the very arguments that Columbia raised were themselves substantially false and misleading. For example, Columbia stated that certain of the new claims were not vulnerable to double-patenting rejections because "none of the claims of the '216 make obvious a recitation of "linked [DNA I and DNA II]." In fact, issued claim 54 of the '216 patent recites transforming a eucaryotic cell "with a molecule which is *formed by linking* one of said foreign DNA I molecules to a DNA II molecule."

46. Columbia also stated that other of the newly added claims were not vulnerable to double-patenting rejections because "none of the claims of the '216 make obvious a recitation that both DNA I and DNA II are amplified." However, issued claim 54 of the '216 patent (for example) recites transforming cells with a molecule formed by linking a DNA I to an amplifiable DNA II, and culturing the transformed cells under conditions "permitting survival or identification of eucaryotic cells which have acquired multiple copies of said amplifiable gene." Because DNA II is an amplifiable gene linked to DNA I, the end result is both amplified DNA I and amplified DNA II. Therefore, contrary to Columbia's assertion, claim 54 does indeed make obvious a recitation that both DNA I and DNA II are amplified.

47. Columbia repeated its misleading and improper statements and omissions in its January 30, 2002 Response.

48. Upon information and belief, Columbia presented these statements with intent to mislead the patent examiner. These misleading statements were material to the examiner's determination of patentability. The '275 patent is therefore unenforceable due to inequitable conduct in its prosecution.

B. Failure to Disclose Rejection of Substantially Similar Claims in '159 Application

49. On June 7, 1995, Columbia filed two continuation applications relying on the original disclosure filed in February 1980. One of these applications matured into the '275 patent. The other, serial No. 08/477,159 ("159 application"), is still pending today.

50. The '159 application included claims directed to subject matter that is substantially similar to the subject matter claimed in the '275 patent. For example, claim 135 of the '159 application was substantially similar to issued claim 14 of the '275 patent.

51. On April 29, 1997, the examiner then assigned to the '159 application issued an Office Action rejecting claims in the '159 application, including claim 135, for double patenting over the '017, '216 and '665 patents. The claims were also rejected for failure to satisfy 35 U.S.C. § 112. Because these claims are substantially similar to claims that issued in the '275 patent, these rejections are highly material to the patentability of those claims.

52. Nonetheless, Columbia did not make the existence of the '159 application of record in the '275 prosecution until April 22, 2002, nearly seven years into the co-pendency of the two applications and a less than three months before the Notice of Allowance of the claims of the '275 patent. Even then, Columbia failed to disclose to the examiner the prior double-patenting rejections, by a different examiner in the '159 application prosecution, of claims substantially similar to those in the '275 application. This withheld information was material to the patentability of the '275 claims.

53. Upon information and belief, Columbia's unreasonable delay in disclosing the '159 application, as well as the failure to disclose rejection of substantially similar claims by a different examiner in that case, was deliberate and intentional. Therefore, the '275 patent is unenforceable due to inequitable conduct in its prosecution.

C. Failure to Disclose the '636 Patent and Rejection of Substantially Similar Claims

54. At about the same time or shortly after he completed the research on which the original '513 application was based, Dr. Axel collaborated with another researcher, James Roberts, to carry out further research on methods of cotransforming eukaryotic cells with foreign DNA encoding genes for producing desired proteins. Based on this research, which was closely related to the work that had led to the '216, '665 and '017 patents, Columbia filed a separate patent application on March 15, 1982. Columbia eventually abandoned this application, serial No. 358,206 ("206 application"), in favor of filing a continuation. It repeated this tactic twice more, ultimately receiving the '636 patent on September 22, 1992, more than a decade after it filed the initial '206 application. Columbia's '636 patent was pending during the prosecution of several of the applications that ultimately led to the '275 patent.

55. The claims of the '636 patent include claims directed to (a) processes for generating multiple copies of a foreign DNA I in eukaryotic cells and (b) product claims directed to eukaryotic and mammalian cells into which foreign DNA I has been introduced by the claimed processes. The claims of the '636 patent overlap in scope with at least claim 5 of the '275 patent and its dependent claims. The '636 patent was prosecuted by the same law firm that prosecuted the '216 patent and related applications (along with foreign counterparts, "216 patent family"), including the '275 patent.

56. Columbia never disclosed the '636 patent to the examiner or made it of record during the prosecution of the '216 patent family, although the '636 patent could have provided a

basis for a double-patenting rejection of various claims in the numerous applications that led to the '275 patent. Thus, the existence of the '636 patent was material to the patentability of claims Columbia prosecuted in the '216 patent family, including at least one claim that issued as part of the '275 patent.

57. The '636 patent file history includes rejections of claims that were substantially similar to claims that were then or later pending during prosecution of the '216 patent family, including the '275 patent. For example, claims 24 and 25 as originally filed in serial No. 06/358,206 ("206 application") (the parent application to which the '636 patent claims priority) are substantially similar to issued claim 5 of the '275 patent. Claims 24 and 25 of serial No. 06/683,251, a continuation of the '206 application, were rejected in an Office Action dated June 3, 1986 as either anticipated by or obvious in view of the '216 patent itself. This rejection, as well as others, evidenced the closeness between the '216 patent family (which includes the '275 patent) and the claims Columbia was seeking in prosecuting the '636 patent. Upon information and belief, those rejections, by a different examiner, were material to the patentability of the claims asserted during the prosecution of the '216 patent family, including the claims that ultimately issued in the '275 patent.

58. Notwithstanding the more than twenty years between the filing of the application that led to the '636 patent and the issuance of the '275 patent, and the many information disclosure statements Columbia filed in the prosecution of the '216 patent family during that time period, Columbia failed to make the pendency, the issuance, or any part of the file history of the '636 patent of record in any of the applications that led to the issuance of the '275 patent.

59. As the owner of the '636 patent as well as the '275 patent, Columbia was aware of the materiality of the '636 patent and its file history to the '275 patent, as was its patent counsel, who prosecuted both the '636 and the '275 patents. Upon information and belief, Columbia's

failure to disclose the '636 patent or its file history during the prosecution of the '216 patent family was deliberate and intentional. Therefore, the '275 patent is unenforceable due to inequitable conduct in its prosecution.

**D. Failure to Disclose Statements to Congress Inconsistent
with Positions Taken Before the Patent Office**

60. As the expiration date of the '216, '665 and '017 patents loomed, upon information and belief, Columbia embarked on an aggressive lobbying campaign in an attempt to secure from Congress an extension of the '216 patent. Upon information and belief, Columbia attempted to obtain special legislation in the form of an amendment to two different, and unrelated appropriations bills. This effort proved unsuccessful.

61. Upon information and belief, Columbia made numerous statements to Congress that were inconsistent with positions it took in its concurrent prosecution of the '275 patent claims in the PTO. In its statements to Congress, Columbia emphasized the breadth and pioneering scope of the '216 patent, telling Congress that its patent broadly claimed both "cotransformed cells and the process of making them." To the PTO, on the other hand, Columbia argued that the scope of the '216 patent was much more limited. Columbia never disclosed to the PTO during prosecution of the '275 patent the inconsistent representations it made to Congress in 2000, in violation of its duty of candor to the PTO under 37 C.F.R. § 1.56.

62. Columbia also made inconsistent representations to Congress and the PTO on other issues. For example, upon information and belief, Columbia told Congress that the '216 patent covered both linked cotransformation as well as unlinked cotransformation. With respect to linked cotransformation, Columbia told Congress that under the '216 patent, "[t]he genes of interest can be joined together in a single DNA construct prior to their introduction into the cell of interest." Columbia also asserted to Congress that "[t]he Cotransformation process [claimed

in the '216 patent] permit[s] the ... amplification of the gene of interest for the purpose of expressing large amounts of the protein it encoded."

63. In prosecuting the '275 patent, by contrast, Columbia characterized the claims of the '216 patent far differently. Columbia stated, in June 14, 2001 and January 30, 2002 Responses to Office Actions, that "none of the claims of the '216 make obvious a recitation of 'linked' [DNA I and DNA II]." Columbia also stated that "none of the claims of the '216 make obvious a recitation that both DNA I and DNA II are amplified."

64. Thus, Columbia's assertions to Congress of the breadth of the '216 patent directly contradict its statements to the examiner of the '275 patent. Columbia never disclosed its statements to Congress to the PTO or advised the examiner that it had taken contrary positions as to the scope of the '216 claims. Upon information and belief, Columbia's failure to disclose these inconsistent statements to the PTO was deliberately misleading. Had these statements to Congress been submitted to the PTO, the examiner would have found them to be material to patentability. The '275 patent is therefore unenforceable for inequitable conduct.

65. Accordingly, for the reasons set forth above and others, Wyeth desires a declaratory judgment that the '275 patent is unenforceable because of inequitable conduct committed during its prosecution.

66. Wyeth, therefore, respectfully seeks judgment as hereinafter set forth.

FOURTH CLAIM FOR RELIEF

Declaratory Judgment that Wyeth Owes no Royalties Under the '275 Patent or any Pending Related Application

67. Wyeth incorporates and realleges all prior paragraphs of this complaint.

68. An actual controversy has arisen and now exists between Wyeth and Columbia concerning whether, as Columbia contends, Wyeth owes royalties under the License Agreement

on the basis of the '275 patent, and/or its patent application, and/or any additional pending patent applications claiming priority to the '513 application.

69. Wyeth maintains that, for each of the reasons set forth above, all the claims of the '275 patent are invalid and unenforceable and therefore the License Agreement does not require Wyeth to pay royalties and fees to Columbia based on the '275 patent.

70. Accordingly, Wyeth desires a declaratory judgment that Wyeth does not owe Columbia royalties and fees under the License Agreement because the '275 patent is invalid and unenforceable.

71. Wyeth seeks the return of any royalties and fees paid to Columbia under the License Agreement before or after filing this lawsuit based on activities occurring after August 16, 2000. Wyeth is entitled to recoup amounts paid under the License Agreement based on the '275 patent after Wyeth gives notice to Columbia that Wyeth is contesting the '275 patent's validity. This complaint gives such notice. Accordingly, Wyeth desires a declaratory judgment that Columbia must repay to Wyeth any amounts paid under the License Agreement based on activities occurring after August 16, 2000.

72. Wyeth, therefore, respectfully seeks judgment as hereinafter set forth.

FIFTH CLAIM FOR RELIEF

Declaratory Judgment that Wyeth has no Contractual Royalty Obligation Because the License Agreement does not Provide for Royalty Payments Based on Pending Patent Applications

73. Wyeth incorporates and realleges all prior paragraphs of this complaint.

74. Columbia maintains that royalties and fees are owed under the License Agreement for activities occurring between the expiration of the original three patents on August 16, 2000 and the issuance of the '275 patent on September 24, 2000 on the basis of pending patent

applications. Wyeth maintains that royalties and fees are not owed to Columbia under the License Agreement for that time period.

75. The express terms of the License Agreement do not provide for royalty or fee payments unless and until a patent issues.

76. Accordingly, no royalties or fees are due on the basis of any pending patent applications.

77. Wyeth desires a declaratory judgment that no royalties and fees are due on the basis of pending patent applications, and further that Columbia must repay to Wyeth any amounts paid to Columbia under the License Agreement for activities occurring between August 16, 2000 and September 24, 2002.

78. Wyeth, therefore, respectfully seeks judgment as hereinafter set forth.

SIXTH CLAIM FOR RELIEF

**Declaratory Judgment that the '275 Patent is Unenforceable by
Reason of Patent Misuse**

79. Wyeth incorporates and realleges all prior paragraphs of this complaint.

80. Columbia maintains that royalties and fees are owed under the License Agreement for activities occurring after August 16, 2000 on the basis of pending patent applications, including the patent application that issued as the '275 patent. Wyeth maintains that royalties are not owed Columbia under the License Agreement after August 16, 2000 on the basis of the '275 patent, neither while it was a pending patent application nor after its issuance on September 24, 2002.

81. Wyeth maintains that the '275 patent is unenforceable due to patent misuse because Columbia seeks unlawfully to extend its patent monopoly by claiming that Wyeth owes royalties and fees under the License Agreement on the basis of the '275 patent not only for activities

occurring after the '275 patent issued, but also for activities occurring in the period from August 16, 2000 through September 24, 2002, after the '216, '665 and '017 patents had expired, and before the '275 patent issued.

82. Accordingly, Wyeth desires a declaratory judgment that the '275 patent is unenforceable against Wyeth due to patent misuse, and a declaratory judgment that Wyeth does not owe royalties and fees claimed by Columbia, either before the '275 patent issued or after it issued.

83. Wyeth desires a declaratory judgment that Columbia must repay to Wyeth any amounts paid to Columbia under the License Agreement based on any pending applications for activities between August 16, 2000 and September 24, 2002, the time period between the expiration of the '216, '665, and '017 patents and the issue date of the '275 patent.

84. Wyeth further desires a declaratory judgment that Columbia must repay to Wyeth any amounts paid to Columbia under the License Agreement based on the '275 patent for activities from September 24, 2002, the issued date of the '275 patent, forward.

85. Wyeth, therefore, respectfully seeks judgment as hereinafter set forth.

SEVENTH CLAIM FOR RELIEF

Declaration that the '275 Patent is Unenforceable Against Wyeth Because Columbia is in Breach of the License Agreement

86. Wyeth incorporates and realleges all prior paragraphs of this complaint.

87. Columbia's actions and conduct, including, *inter alia*, demanding royalty payments based on pending applications and the '275 patent, constitute a material breach of Section 2(b) of the License Agreement.

88. Section 2(b) of the License Agreement provides that "All rights granted by Columbia under this agreement are subject to any rights required to be granted to the

Government of the United States of America, including without limitation any rights reserved or obligations imposed by the Government pursuant to 35 U.S.C. § 200-211 [i.e., the Bayh-Dole Act], regulations thereunder and the determination letter to Columbia from the Department of Health and Human Services dated February 24, 1981, a copy of which is attached hereto...” These rights and obligations referred to in Section 2(b) are expressly incorporated into the License Agreement, and include the rights and obligations imposed by (1) the laws, regulations, federal public policy statements, and/or agreements referred to or set forth in the Columbia/HHS letter agreement granting title to the original patent application to Columbia, (2) the conditions and/or requirements which predicated HHS’s grant of title to the original patent application to Columbia, which are set forth in the Columbia/HHS letter agreement, and (3) the provisions of the Bayh-Dole Act (35 U.S.C. §§ 200-212) and its implementing regulations (37 C.F.R. part 401).

89. Wyeth maintains that Columbia is in breach of Section 2(b) of the License Agreement because Columbia’s actions and conduct, including, *inter alia*, demanding royalties and fees under the License Agreement after August 16, 2000 on the basis of the ‘275 patent and/or pending patent applications, violates, and are antithetical to the spirit and intended purpose of, the laws and regulations under which the federal government granted title to the invention to Columbia, which include, *inter alia*, the laws, regulations, federal public policy statements, and/or agreements referred to or set forth in the Columbia/HHS letter agreement to Columbia granting title to the original patent application to Columbia.

90. Columbia is in further breach of Section 2(b) of the License Agreement because Columbia’s actions and conduct violates, and are antithetical to, the conditions and/or requirements which predicated HHS’s grant of title to the subject invention to Columbia, which are set forth in the Columbia/HHS letter agreement.

91. Columbia also is in breach of Section 2(b) of the License Agreement because Columbia's actions and conduct violates, and are antithetical to the spirit and intended purpose of, provisions of the Bayh-Dole Act (35 U.S.C. §§ 200-212) and its implementing regulations (37 C.F.R. part 401).

92. Accordingly, Wyeth desires a declaratory judgment that Columbia is in breach of Section 2(b) of the License Agreement and that this breach is material. Wyeth also desires a declaratory judgment that because of this breach, the '275 patent and pending patent applications related to the '513 application are unenforceable against Wyeth.

93. Wyeth further desires a declaratory judgment that due to this material breach, Wyeth is under no obligation to pay royalties and fees based on activities occurring after August 16, 2000.

94. Wyeth, therefore, respectfully seeks judgment as hereinafter set forth.

EIGHTH CLAIM FOR RELIEF

**Declaration that Columbia is in Breach of its Agreement with
the HHS and Wyeth is Entitled to Relief as a Third-Party
Beneficiary to the Columbia/HHS Letter Agreement**

95. Wyeth incorporates and realleges all prior paragraphs of this complaint.

96. Wyeth is a third-party beneficiary to the Columbia/HHS letter agreement. The Columbia/HHS letter agreement and the laws, including the Bayh-Dole Act, regulations, federal public policy statements, and/or agreements referred to therein, establish that licensees, including Wyeth, are intended beneficiaries of the Columbia/HHS letter agreement.

97. Columbia is in breach of the Columbia/HHS letter agreement because Columbia's actions and conduct, including, *inter alia*, demanding royalties and fees under the License Agreement after August 16, 2000 on the basis of the '275 patent and/or pending patent

applications, violates, and are antithetical to the spirit and intended purpose of, (1) the laws, regulations, federal public policy statements, and/or agreements referred to or set forth in the Columbia/HHS letter agreement, (2) the conditions and/or requirements which predicated HHS's grant of title to the original patent application to Columbia, which are set forth in the Columbia/HHS letter agreement, and/or (3) the provisions of the Bayh-Dole Act (35 U.S.C. §§ 200-212) and its implementing regulations (37 C.F.R. part 401). Because of this breach, Wyeth, as a third-party beneficiary to the Columbia/HHS letter agreement, is entitled to the relief set forth in the Columbia/HHS letter agreement and/or the Bayh-Dole Act. Accordingly, Wyeth maintains that it is entitled to a royalty-free license to the '275 patent and any pending patent applications related to the '513 application.

98. Accordingly, Wyeth desires a declaratory judgment that Columbia is in breach of the Columbia/HHS letter agreement and that because of this breach by Columbia, Wyeth, as a third-party beneficiary to the Columbia/HHS letter agreement, is entitled to a royalty-free license to the '275 patent and any pending patent applications related to the '513 application.

99. Wyeth, therefore, respectfully seeks judgment as hereinafter set forth.

NINTH CLAIM FOR RELIEF

Declaration that Wyeth has no Contractual Royalty Obligation Because Columbia is in Breach of its Implied Duty of Good Faith and Fair Dealing

100. Wyeth incorporates and realleges all prior paragraphs of this complaint.

101. Columbia's actions and conduct constitute a breach of its implied duty of good faith and fair dealing with Wyeth. Columbia's actions and conduct, include, *inter alia*, unreasonably delaying the prosecution of the patent applications that led to the '275 patent; obtaining an invalid and unenforceable patent; failing to adhere to the requirements for patentability when prosecuting these patent applications; and failing to adhere to the terms, spirit and intended

purpose of HHS's grant of title of the original patent application to Columbia, as set forth or referred to in the Columbia/HHS letter agreement and the Bayh-Dole Act (35 U.S.C. §§ 200-212), and then attempting to seek royalties and fees until 2019—nearly tripling the term of the License Agreement.

102. Columbia has acted in bad faith to destroy or injure the rights of, or implied covenants promised to, Wyeth under the License Agreement. These rights or covenants include, *inter alia*, the expectation that after paying millions of dollars in royalties for the Axel patents, these royalty payments would end after a reasonable term as measured by the life of the Axel patents, and at that time, the inventions would pass into the public domain and the public, including Wyeth, could practice the inventions free from any royalty obligations.

103. Columbia's actions and conduct further demonstrate its failure to observe reasonable commercial standards and fair dealing by attempting to force Wyeth, through its bad faith actions and conduct, to potentially pay royalties and fees under the License Agreement for a total of twenty-nine years, an additional nineteen years after the Axel patents expired.

104. Accordingly, Wyeth desires a declaratory judgment that Columbia is in breach of its implied duty of good faith and fair dealing with Wyeth, and that because of this breach, Wyeth is under no obligation to pay royalties and fees to Columbia on the basis of the '275 patent, its patent applications, and any pending patent applications related to the '513 application.

105. Wyeth, therefore, respectfully seeks judgment as hereinafter set forth.

TENTH CLAIM FOR RELIEF

Declaratory Judgment that Wyeth has no Contractual Royalty Obligation Because Wyeth is Entitled to an Implied License to the '275 Patent Based Upon Legal Estoppel

106. Wyeth incorporates and realleges all prior paragraphs of this complaint.

107. Wyeth is entitled to an implied, royalty-free license to the '275 patent because Columbia, by demanding royalties under the License Agreement on the '275 patent after receiving millions of dollars in royalties on the '216, '665 and '017 patents until their expiration on August 16, 2000, seeks to derogate the right it granted to Wyeth under the License Agreement.

108. Accordingly, Wyeth desires a declaratory judgment that the '275 patent is unenforceable against Wyeth because Wyeth is entitled to an implied, royalty-free license to the '275 patent because Columbia's actions improperly seek to derogate the right it granted to Wyeth under the License Agreement, and for which it received valuable consideration. Wyeth also desires a declaratory judgment that it does not owe royalties and fees claimed by Columbia on the basis of the '275 patent, either before the '275 patent issued or after it issued, or on the basis of any pending patent applications.

109. Wyeth, therefore, respectfully seeks judgment as hereinafter set forth.

ELEVENTH CLAIM FOR RELIEF

Declaration of an Exceptional Case

110. Wyeth incorporates and realleges all prior paragraphs of this complaint.

111. Wyeth desires a declaratory judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and that they are entitled to an award of attorneys' fees, costs, and expenses.

112. Wyeth, therefore, respectfully seeks judgment as hereinafter set forth.

PRAYER FOR RELIEF

WHEREFORE, Wyeth prays for relief as follows:

a. For a preliminary and permanent injunction, and a declaration that the '275 patent is invalid and unenforceable because each of the inventions claimed in it is identical to, or is merely an obvious variation of, the inventions claimed in the '216, '665 and/or '017 patents.

- b. For a preliminary and permanent injunction, and a declaration that the '275 patent is invalid for failing to satisfy one or more of the statutory conditions of patentability set forth in 35 U.S.C. § 102, § 103 and § 112;
- c. For a preliminary and permanent injunction, and a declaration that the '275 patent is invalid and unenforceable because of prosecution laches;
- d. For a preliminary and permanent injunction, and a declaration that the '275 patent is unenforceable because of inequitable conduct committed during its prosecution;
- e. For a preliminary and permanent injunction, and a declaration that Wyeth is under no obligation to pay Columbia royalties and fees under the License Agreement on the basis of the '275 patent;
- f. For a preliminary and permanent injunction, and a declaration that Wyeth is under no obligation to pay Columbia royalties and fees under the License Agreement on the basis of pending patent applications;
- g. For a preliminary and permanent injunction, and a declaration that the '275 patent is unenforceable against Wyeth because demanding royalties on the '275 patent during its term and/or before it issued is patent misuse;
- h. For a preliminary and permanent injunction, and a declaration that the '275 patent and pending patent applications are unenforceable against Wyeth due to (1) Columbia's breach of Section 2(b) of the License Agreement and/or (2) Columbia's breach of its agreement with HHS, of which Wyeth is third-party beneficiary;
- i. For a preliminary and permanent injunction, and a declaration that Columbia breached its implied duty of good faith and fair dealing with Wyeth;
- j. For a preliminary and permanent injunction, and a declaration that the '275 patent and any pending patent applications are unenforceable against Wyeth and that Wyeth is

entitled to an implied, royalty-free license to the '275 patent and any pending patent applications because Columbia is seeking to derogate the right it granted to Wyeth under the License Agreement;

k. For a declaration that Columbia must repay to Wyeth any amounts paid under the License Agreement based on activities occurring between August 16, 2000 and September 24, 2002, and based on activities occurring from September 24, 2002 forward;

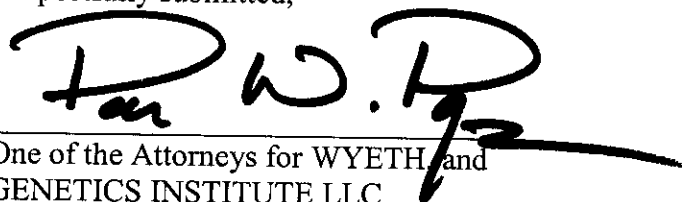
l. For a declaration that Columbia must repay Wyeth any post-filing amounts under the License Agreement;

m. For attorneys' fees, costs and expenses of suit; and

n. For such other, further and additional relief as the Court may deem just and appropriate.

Dated: August 20, 2003.

Respectfully submitted,



One of the Attorneys for WYETH and
GENETICS INSTITUTE LLC

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